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A Biomechanical Comparison of Micromotion After Ankle Fusion Using 2 Fixation Techniques: Intramedullary Arthrodesis Nail or Ilizarov External Fixator

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ABSTRACT

Background: **In difficult ankle arthrodesis situations, intramedullary (IM) arthrodesis nails and external fixation are often considered in lieu of standard fusion techniques. The purpose of this study was to compare the amount of micromotion measured across an ankle fusion site stabilized with either an IM nail or with the Ilizarov external fixator.** ***Materials and Methods:*** **The relative bone mineral density of 8 pairs of human cadaveric lower legs was measured by DEXA scanning. One specimen from each pair was randomly assigned to be stabilized with a new generation IM nail and the other with an Ilizarov external fixator. Specimens were tested in compression, rotation, and dorsiflexion. Optical motion capture was used to measure the direct motion occurring at the fusion site.** ***Results:*** **No significant difference was found between the axial displacements ($p = 0.94$), torsional displacement ($p = 0.07$), or the dorsiflexion angular displacement ($p = 0.28$) for the IM rod group and the external fixation group. A weak correlation was found between BMD and displacement.** ***Conclusion:*** **Both the new generation IM nail and the Ilizarov external fixator imparted excellent stability to the fusion site despite a wide range of bone mineral densities. Medialization of the talus, the ability to compress the nail, and the addition of a posterior-to-anterior locking screw were thought to improve the performance of the nail.** ***Clinical Relevance:*** **Both IM nail and Ilizarov external fixation provided excellent fusion site stability. The decision of which implant to use for complex arthrodesis should be dictated by the clinical needs.**

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INTRODUCTION

Ankle arthrodesis is a reliable means of providing pain relief, restoring joint stability, and realigning lower extremity deformity in patients with advanced ankle arthrosis. Popular methods for stabilizing an ankle fusion include crossed lag screws, plate and screws, retrograde intramedullary (IM) nailing, and external fixation.[7,11,12,20] Both IM nailing and external fixation are typically reserved for arthrodesis of more complex ankle pathology and limb salvage situations.[13,18,21,24,25,28,29,34] Bone loss from the tibial plafond or the talus, significant deformity, osteomyelitis, poor bone quality, poor skin or soft tissue envelope, and the presence of Charcot neuropathic joint destruction are factors that increase the complexity of ankle arthrodesis. Many of these patients have failed multiple previous surgeries and suffer from medical comorbidites such as diabetes mellitus, peripheral vascular disease, rheumatoid arthritis, and smoking history, all of which add to the complexity of the fusion. Obtaining a solid fusion can be challenging at these compromised bony interfaces, and standard techniques of tibiotalar fixation with crossed lag screws are often inadequate.[2]

An IM device is frequently used in these situations because it provides stability and can be inserted with less invasive surgery relative to other open techniques. Orthopaedic surgeons are comfortable using IM implants, and compression can be implemented at the time of surgery. Newer generation IM nail designs have increased stability over older nails.[16] However, the IM technique requires violation of the subtalar joint, the locking bolts may provide suboptimal purchase in compromised bone, and IM fixation is contraindicated in the presence of infection. McGarvey[17] showed the potential risk of neurovascular injury if the calcaneus is not medialized before nail insertion. When using a nail, deformity must be corrected at the time of nail insertion, typically requiring an acute correction with the risk of stretching or kinking vessels and nerves. The reported incidence of nonunion with IM nail ankle arthrodesis is as high as 57% in complex situations.[6,24]

The Ilizarov method provides a versatile modular approach to deal with all aspects of post-traumatic ankle reconstruction.[21,25] Problems with poor skin, compromised circulation, and poor bone quality are minimized. In situations of bone loss, bone graft can be added or simultaneous lengthening can be performed. No internal hardware is used, making this method ideal for cases of infection and poor wound healing potential. Malalignment can be corrected initially and fine-tuned throughout the course of the treatment, or deformity can be corrected gradually either with hinges or by using the specially designed computer-assisted Taylor Spatial Frame (Smith + Nephew, Memphis, TN).[8,27] The subtalar joint is preserved during treatment by not violating its articular surface and through local distraction placed across that joint at the time of frame application. Compression at the fusion site is applied at surgery and can be increased throughout the postoperative treatment period. Problems with the Ilizarov frame include its bulky nature, pin tract infections, the need for patient support at home to ensure compliance with treatment, and the prolonged time in the frame, which is typically 4 to 6 months.

The purpose of this investigation was two-fold. First, we wanted to compare the stability imparted to the fusion site by the Biomet Ankle Arthrodesis Nail (Warsaw, IN) and the Ilizarov/ Taylor Spatial Frame through a range of bone mineral densities (BMD) under testing conditions that simulated immediate post operative full weightbearing. Second, we wanted to explore the use of a highly accurate motion capture system to pinpoint the motion across the fusion site (local motion) and compare those values to total motion across the entire specimen and testing system (global motion). Local motion analysis would allow us to base our comparison of the 2 fixation techniques on bony displacements occurring at the fusion instead of calculating global stiffness values of the bone-implant constructs.

MATERIALS AND METHODS

Eight paired human cadaver lower legs (average age, 65 years old; range, 50 to 75 years) were used for this study. The specimens were fresh frozen with a maximum of 3 freeze-thaw cycles which has been shown by Panjabi et al.[22] to not cause a significant change in mechanical properties. A DEXA scan of the calcaneus using an R1 subregion array spine protocol technique was performed to determine the relative projectional BMD before the soft tissues were removed for testing. The mean projectional BMD was 0.469 g/cm^2 (range, 0.169 to 0.672 g/cm^2). The standard deviation for calcaneal BMD was 0.16g/cm^2. The tibia were transected at mid-diaphysis, and the proximal portion discarded. The specimens were dissected free of soft tissues. The fibula was excised, and the joint surfaces were prepared with flat cuts. The distal 5 to 10 mm of the tibial plafond was resected with the medial malleolous. The proximal 5 mm of the talar body was resected. The calcaneus was medialized to lie in-line with the tibia. The surfaces provided maximal bony contact and preserved extremity alignment. The position of the foot and ankle was plantigrade, in 10 degrees of external rotation, and in zero to 5 degrees of hindfoot valgus. The subtalar joint was not prepared for fusion, because for the majority of Ilizarov ankle fusions the subtalar joint is preserved.

One lower extremity of each cadaver pair was randomly assigned to receive IM nail fixation or fixation with an Ilizarov frame. The contralateral extremity received the opposite fixation method. Canal preparation and nail insertion were performed according to the manufacturer's surgical protocol. A guide wire was placed in a retrograde fashion through the calcaneus, talus, and into the intramedullary canal of the distal tibia. Successive reaming ensued until cortical chatter was perceived. A nail was selected that was 0.5 to 1.0 mm less in diameter than the largest reamer used. The nail was inserted so that its end was buried 5 mm deep to the calcaneal cortex. The average nail diameter was 10 (range, 10 to 12) mm, and all nails were 150 mm long. Proximal locking was accomplished with the targeting guide using two 5-mm screws in the tibial diaphysis. Compression was applied at the fusion site using the nail's compressive mechanism. Three 5-mm distal locking screws were used: one calcaneal screw inserted from posterior-to-anterior and another from lateral-to-medial, and one talar locking screw inserted from lateral-to-medial.

The Ilizarov/Taylor Spatial Frame was applied using our standard configuration for ankle fusion. Two 155-mm closed rings were attached to one another with four 150-mm connecting rods. This ring block was mounted to the distal tibia using one tensioned Kirschner wire and one 6-mm half pin off of each ring for a total of four points of fixation in the tibia. A 155-mm long foot ring was closed and then connected to the foot with 3 oblique calcaneal wires, a midfoot wire, and a talar wire for a total of five points of fixation below the fusion. The talar wire was arched proximally such that when it was tensioned, the wire placed a distraction force across the subtalar joint while further compressing the fusion site. All wires were smooth, 1.8 mm in diameter, and tensioned to 130 kg. The foot ring was attached to the distal tibial ring with five 150-mm connecting rods. Ten millimeters of compression was placed across the fusion site.

The proximal tibial diaphysis and foot were potted in Bondo (Bondo Corp., Atlanta, GA) resin. Two custom fixtures were made for the biaxial testing of all the specimens that served as molds for the potting. Bonding of the resin at both ends of the bone was enhanced by the placement of dry wall screws through the metatarsal heads, the calcaneus, and the proximal tibial diaphysis. Great care was taken to ensure that no part of the foot ring or wires came into contact with the resin.

The specimens were mechanically tested in a biaxial load frame (Bionix, MTS, Eden Prairie, MN). Two to three pairs of reflective markers were placed on the specimen both above and below the fusion site (Figure 1), for optical tracking (described below). Three cyclic sinusoidal tests were performed: 1) an axial compressive load was applied at 0.5 Hz from 0-700N, 2) a torsional load was applied to ±5.0 Nm at 0.25 Hz with a constant static 700N compressive load, and 3) a dorsiflexion load was applied at 0.5 Hz from zero to 50 Nm. All tests were conducted to 500 cycles. The test frequencies and loads were chosen to represent ambulation in the early post operative period. The 700-N load approximates full body weight across the fused ankle[30] and was selected to answer the question of whether or not the constructs could support immediate full weightbearing. Although true weightbearing loads can be several times greater than bodyweight, the postoperative patient will place all of their weight on the operated extremity very briefly and their gait will be slow to minimize the amount of dynamic load across the ankle fusion. Seven hundred Newtons reasonably represents ankle loads in unsupported standing and slow supported walking. The 50-Nm dorsiflexion moment was calculated from the distance from the center of the ankle to the ball fixture times a half-body weight load (142 mm x 350 N) (Figure 2). The frequencies of 0.25 and 0.5Hz represent a slower than normal walking speed. Although the outputs from the mechanical tests settled into a reproducible pattern after 10 cycles, testing was continued to 500 cycles before taking final measurements as these better represented forces applied over time soon after surgery.

Fig. 2: This specimen, stabilized with an IM nail, is seen here in the dorsiflexion testing set-up with an unconstrained fulcrum under the distal foot. Angular displacements were calculated from local motion measurements recorded in this position.

Optical data were recorded every 100 cycles using a three-camera Qualisys Track Manager (Qualisys, Gothenburg, Sweden) motion capture system (Figure 3). The manufacturer's stated error for the motion measurement was 0.03 mm for the marker size, the refresh rate, and the distance from camera to specimen used. The relative axial and angular displacements were calculated across the osteotomy site from the motions of each marker.

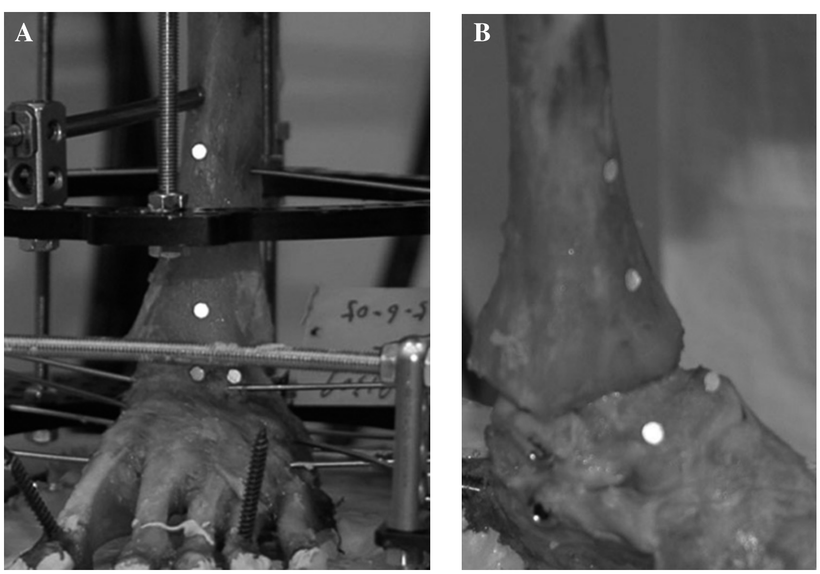

Fig. 1: Reflective markers were applied to both the tibia (A) and talus (B) for the cameras to capture motion at the fusion site. Although three pairs of markers were used in several tests, often only two were seen by the cameras due to obstruction from the external fixator.

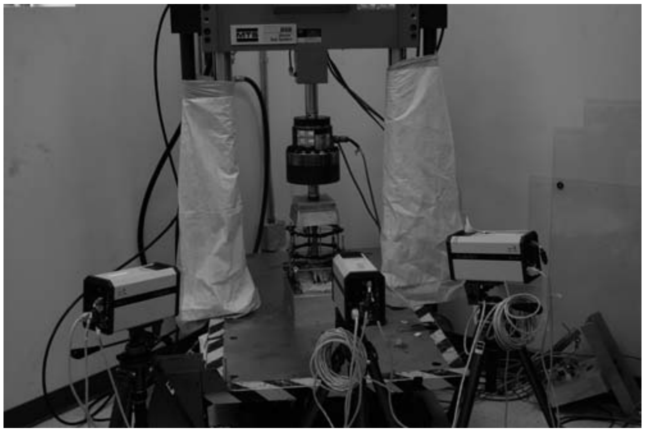

Fig. 3: The specimen is seen fixed in the biaxial materials testing machine. Three cameras were used to track the reflective markers during load testing. Motion across the ankle fusion site during loading was captured and accurately measured.

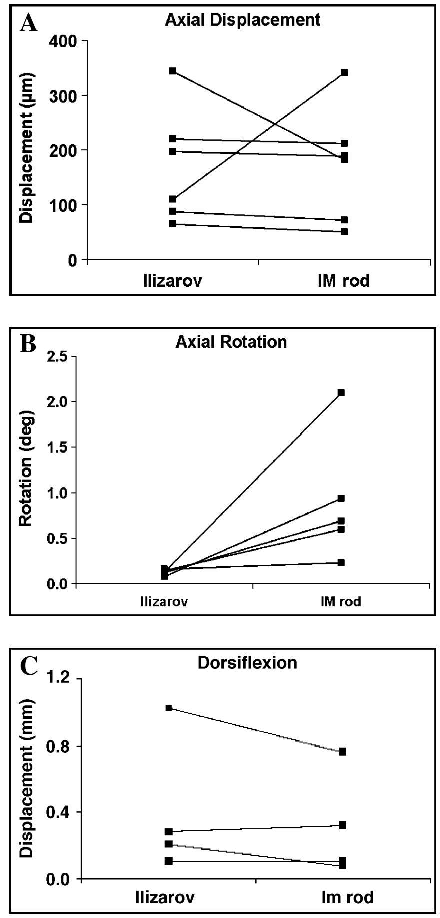

Fig. 4: **A**, In axial loading, the method of fixation did not significantly alter displacements measured. **B**, With torsional testing, the Ilizarov fixator exhibited a trend toward increased stability over the IM nail, but this was not significant ($p = 0.07$). **C**, In dorsiflexion testing, displacement showed no difference between Ilizarov and IM nail groups.

Statistical Methods

A power analysis was performed assuming that the standard deviation given for nail stability in previous studies would be similar to this study and that the Ilizarov fixator would provide 50% to 100% greater stiffness than the IM nail. Given these assumptions, 7 paired cadavers would give a power of 0.83 to detect a 50% increase in bending stiffness and a power of 0.99 to detect a 100% increase in torsional stiffness with alpha set to 0.05. Paired t-tests were used to compare the motions between the 2 fixation types. Pearson Correlations and first order linear regression were used to determine if BMD affected the amount of rotation or displacement found. Significance was determined for all tests as $p \leqslant 0.05$.

RESULTS

No significant difference ($p = 0.94$) was found between the axial displacements for the IM rod group ($150 \pm 120\mu$m) and the external fixation group ($170 \pm 100\mu$m) (Figure 4A). The average relative torsional angular displacement for the IM rod group was 0.91 degrees (± 0.71 degrees), for the external fixation group was -0.31 degrees (± 0.33 degrees) ($p = 0.07$) (Figure 4B). Three specimens were damaged during the dorsiflexion testing. Of the remaining four pairs, no significant difference ($p = 0.28$) was found in angular displacement between the IM rod group (0.31 ± 0.27 mm) and the external fixation group (0.45 ± 0.35 mm) (Figure 4C). A second power analysis was run to determine the minimal detectable difference between micromotions of the 2 fixation configurations using the number of specimens that we eventually had. The minimal detectable differences were 0.13 mm for the axial test, 0.91 degrees for the torsion test, and 0.75 mm for the dorsiflexion test. In the Global motion data, as measured by the MTS machine, there was no significant difference between the IM rod and external fixation groups in any of the tests.

Global motion was compared to the local motion, as measured by the optical tracking system. There was a direct correlation between the global and local measurements with the global measurements being 2 to 16 times greater than the local recordings (Figure 5, A and B). The global data was significantly larger than the local data in all cases (axial loading: external fixator $p = 0.001$, IM nail $p = 0.006$; torsion: external fixator $p = 0.05$, IM nail $p = 0.003$; dorsiflexion: external fixator $p = 0.001$, IM nail $p = 0.03$). A very weak correlation (R^2) was found between BMD and displacement (Figure 6), but using Pearson correlation no displacements or rotations were found to be affected significantly by BMD (IM rod: displacement $p = 0.38$, rotation $p = 0.14$; external fixation: displacement $p = 0.13$, rotation $p = 0.46$).

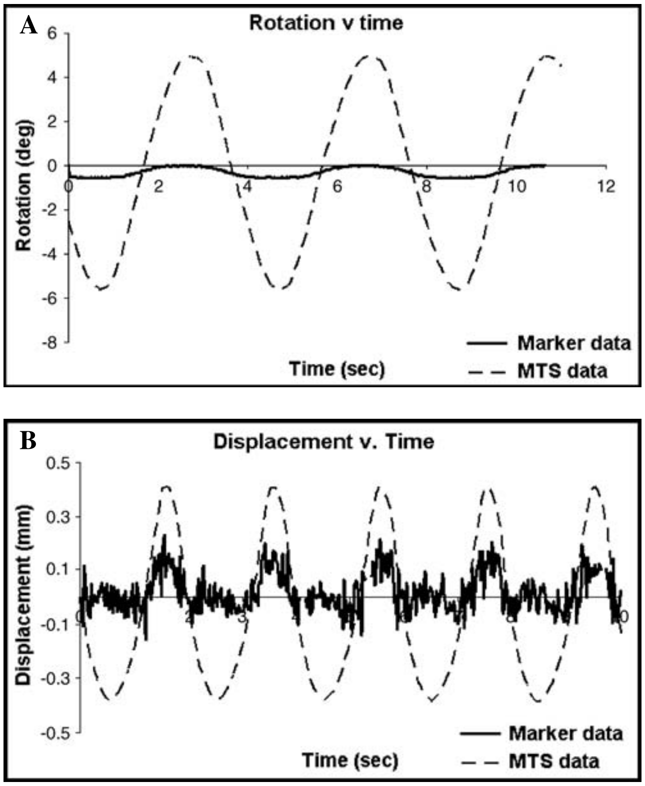

Fig. 5: Global displacement (dotted line), as measured by the materials testing machine, is seen to be over 16 times greater than local displacement (solid line), measured using motion capture. As global displacement includes all motion occurring throughout the testing system, local displacement measurements are more specific for movement at the fusion site and are therefore more meaningful. This was demonstrated while testing both rotation (A) and axial displacement (B).

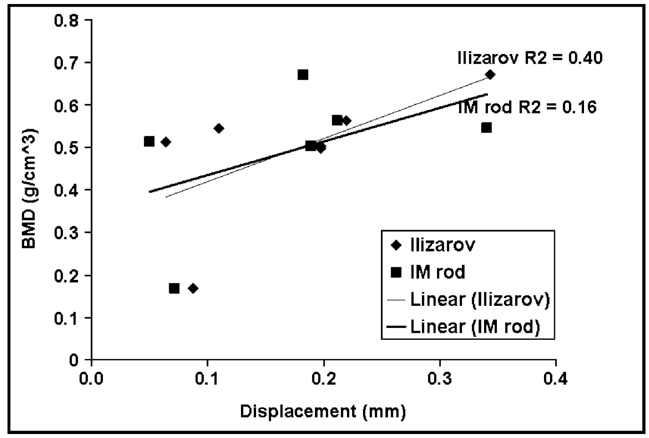

Fig. 6: R^2 values demonstrate a very weak correlation between bone mineral density and displacement using either means of fixation. This implies that both fixation devices perform well throughout a range of bone mineral densities.

DISCUSSION

A concern in ankle fusion is that early postoperative ambulation will result in excessive motion at the fusion site and lead to nonunion. How much motion is allowable or even advantageous remains unknown. Previous studies concentrated on measuring and comparing the relative stiffness of different fixation devices and techniques[1,4,5,9,31–33] using global motion measured across the entire testing apparatus, which included contributions from movements anywhere in the load train, including the fixtures and measuring devices. Any elasticity in the tibial diaphysis will be included in these types of displacement measurements as well. In previous studies the average axial displacement was on the order of 2.6 to 6.0 mm[1,5] and the average angular displacement was 4 to 12.6 degrees.[1,32] Our average recorded local displacements were much lower: 160μm (range, 50 to 340μm), 0.61 degrees (range, 0.08 to 2.09 degrees), and 0.39 (range, 0.08 to 1.02) mm for axial, torsional, and dorsiflexion, respectively. We attribute this finding to the ability of our optical measuring device to exclude the other extraneous motions in the test system. Our global motion measurements, however, showed larger rotations (0.98 to 7.6 degrees) and displacements (range, 0.4 to 1.4 mm) similar to those reported in other studies.

Most cadaveric biomechanical studies of ankle and tibiotalocalcaneal (TTC) fusion constructs have striven to minimize motion between the MTS testing machine and the specimens. This is accomplished by shortening the length of tibial diaphysis, removing the calcaneus and foot, or in the case of a TTC fusion, removing the foot distal to Chopart's joint. By stripping down the specimen nearly all recorded motion should be occurring at the fusion site. In our experiment we strove to maintain a physiologic model of the foot and ankle. Most of the tibial diaphysis was retained. The midfoot and forefoot including ligaments were retained. The metatarsals were fixed to the fixture along with the calcaneus. The subtalar joint was not prepared and therefore served as a point of motion particularly in the Ilizarov fixator group where only one Kirschner wire was used to hold the talus. In the IM nail group the subtalar joint was fixed by the nail but still served as a point of motion. There was motion between the specimen and the resin. There was motion between the fixture and the resin that held the specimen at both ends. In our attempt to test a more physiologic foot model the system allowed for extraneous motion (away from the fusion site). A direct comparison of our global displacement measurements with those obtained in other studies was performed. In previous studies the average axial displacement was on the order of 2.6 to 6.0 mm[1,5] and the average angular displacement was 4 to 12.6 degrees.[1,32] Our average globally measured axial displacement was 0.8 (range, 0.4 to 1.4) mm, less than that seen in previous studies. Our globally measured angular displacement was 2.8 degrees (range, 1.0 to 7.6 degrees), similar to other studies. These results support the contention that by retaining the foot with the ankle specimen and including it in the testing one may achieve a more physiologic model and not compromise ultimate stability. There was a linear relationship between our global and local displacement measurements, but local motion measurements were significantly smaller in magnitude. Bennett et al.[3] also looked at local motion analysis in a tibiotalocalcaneal arthrodesis model. In that experiment, very small displacements were recorded at both fusion sites using strain gauges. They stated that they were able to accurately detect motions as small as 10μm using their technique.

We had hypothesized that the Ilizarov frame would provide superior stability, particularly in torsion. Furthermore, we reasoned that the external frame with its all-wire foot connections would produce a trampoline effect when subjected to axial loading, producing greater axial displacements than the nail. Our findings did not support the hypothesis as the nail and the frame provided comparable axial and dorsiflexion stability and excellent torsional stability. The reason that very little axial displacement was seen may result from the well apposed flat fusion surfaces and the strong compressive forces delivered across the fusion site during specimen preparation. The unexpectedly strong performance of the nail in torsion was probably related to techniques that were not utilized in other recent studies: the medial maleolous was removed, and the calcaneus and talus medialized providing more calcaneal bone stock for the nail to pass through; a long posterior-to-anterior calcaneal locking bolt was used, which is known to increase torsional stiffness;[16] three distal locking screws were used in the talus and calcaneus; strong compression was applied prior to distal locking; and a 700 N static axial load was applied during testing increasing friction between the fusion surfaces.

Though both techniques are clinically effective, no biomechanical studies exist comparing the stability of these implants in the setting of ankle arthrodesis. Berend, et al.[4] compared the stiffness of an IM nail to two lag screws in a tibiotalocalcaneal arthrodesis cadaver model and found that the IM nail provided more than twice the stiffness of the lag screws in bending and in torsion. In a similar model, Bennett[3] showed that adding a third crossed lag screw dramatically improved stiffness over the locked retrograde IM nail. When the IM nail was augmented with a tibiotalar staple, the stability of the nail was comparable to that of the three screws.

Chiodo, et al.[5] examined IM nail and blade plate stiffness in a paired cadaver study of ankle fusion. DEXA scanning of the specimens was performed for later correlation between fixation technique and relative bone mineral density (BMD). An additional compression lag screw was used to augment the plate fixation. Specimens were tested in dorsiflexion. The stiffness provided by the plate was significantly greater than that provided by the nail, and the blade plate was more stable compared with an IM nail in bone with low BMD. They suggested that a nail should not be used in osteoporotic bone if possible. The study has since been criticized for using extra fixation with a compression lag screw in the blade plate group, but not in the nail group.[14,19] This selective augmentation may have unfairly improved the stability in plated specimens. Other factors may have contributed to poor nail performance in that study; the joint surfaces were not prepared, the calcaneus was not medialized requiring the nail to be inserted through its medial portion where less bone stock exists, and an older model arthrodesis nail was used that allowed for only two distal locking screws, neither of which was in the sagittal plane.

Alfahd et al.[1] reported contrary findings in comparing IM nail to blade plate fixation of ankle fusions in a paired cadaver study. Angular displacements were recorded in multiple planes during cantilever and torsional loading. BMD was determined post testing from histological sampling of the cadaver bone. The stability of the plate and the nail were comparable. Both fixation techniques showed decreased stability in torsion with lower BMD. No correlation was found between BMD and fixation technique between a blade plate and an IM nail. They did not use a supplemental lag screw in the plated group. In our study, relative BMD did not affect implant stability. This implies that the choice of fixation could be made without considering the patient's BMD as a major factor.

The ankle arthrodesis nails used in the previous studies were first generation nails. Mann et al.[16] studied a different ankle fusion IM nail design where a calcaneal locking screw was inserted from posterior-to-anterior instead of from lateral-to-medial. They showed that the torsional stiffness of the nail with the posterior-to-anterior screw was superior to that with the coronal plane locking screw.

Thordarson et al.[32] compared the mechanical properties of multiple external fixation frame constructs (non-circular) in a cadaver model. Manual application of bending and rotation forces demonstrated the excellent stiffness that external fixation provides in torsion.

Ours is not the first study to use local displacement analysis to evaluate implant stability,[10] but it provides an excellent model for testing the biomechanical properties of ankle fusion techniques. The ability to quantify the motion occurring at the bone healing interface to within microns is a marked advantage over measuring global displacement. These precise motions can be correlated with motion data as it relates to bone healing. How the amount of strain at a bony interface will affect the type of cells that are active and the type of bone healing that can occur at that site has been studied,[23] but the amount of allowable motion to promote healing but prevent nonunion at an ankle fusion site remains unknown. Bony stability is only one factor affecting healing, but it is a factor that can largely be controlled and thus warrants further optimization. The ability to quantify the amount of motion that an implant allows may help with the design of implants and fixation techniques made specifically for the known motion needed for healing at a particular site.

Crossed lag screw and plate and screw constructs were not tested in this study. We were primarily interested in the performance of devices used for complex ankle arthrodesis.

Standard fixation methods are not as reliable in cases of bone loss and where there is a loss of the ankle joint contour. For this reason two common fixation devices used for difficult ankle fusions, the retrograde IM nail and the Ilizarov frame, were selected for this study.

Our study has limitations. The original supposition that the external fixator would demonstrate twice the stiffness of the IM nail led to a power analysis that suggested 7 paired cadavers would be enough to demonstrate significance. The testing then showed that the two fixation methods were quite comparable and that our assumptions were flawed. A greater number of specimens might confirm the significance of the trend observed toward improved rotational stability in the Ilizarov fixator group. An established standard for calcaneal BMD measurements as they relate to the diagnosis of osteoporosis would allow for a more meaningful interpretation of our BMD data. The three-dimensional (3-D) positions of the talus and tibia were not established in many cases as only 2 of the 3 reflective markers were seen by the optical tracking system at times. Two-dimensional positioning allowed for accurate interpretation of the results, but 3-D would have been preferable. Dorsiflexion data were based on too few specimens to show any significant difference between implants. Cycling to greater than 100,000 cycles would have been more representative of fixation endurance over the bulk of the healing period, although all settling was observed after only 10 cycles.

CONCLUSION

In summary, IM nailing and external fixation did not significantly differ from one another in terms of their mechanical performance. Both implants provided excellent fixation with minimal motion at the fusion across a range of bone mineral densities. The choice of which implant to use will depend on the clinical situation. The Ilizarov frame is advantageous when there is a need for simultaneous lengthening, suspicion of infection, need for gradual deformity correction, and a desire to preserve the subtalar joint. Local motion was measured directly at the fusion surfaces using an optical tracking system. This approach provides a direct benefit over those employing global displacement measurements, which include extraneous motion throughout the testing system and therefore may not as accurately reflect the ability of the implant to control motion at the fusion site. Precise displacement measurements across the fusion site provide more meaningful information than stiffness measurements, from which displacements can only be inferred.

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